To: **Eric Olson** - Patent Examiner / **Shaojia Anna Jiang** – Supervisory Patent Examiner
Art Unit: 1623 Application/Control Number: 10/627,358 - Peter Migaly
PTO fax phone: 571-273-8300 phone :(571)272-0627
From: Peter Migaly: migaly1@earthlink.net, FAX:(724)327-8887, cell phone:(724)840-0464
Re: Question for clarification (Total # of pages:1)
Dear Eric Olson, and/or Shaojia Anna Jiang, October 12, 2006

I have received your 1st office action from my attorney on September 21st 2006, leaving me about a month to reply. My attorney had expressed that he is curious of my reply, but suddenly he left for a vacation and will be back only on October 18, 2006. Therefore now I'm quite **alone** in crafting my answer, and I need to rely on your clarification and accurate data to reply:

On page 12 of your 1st office action, second paragraph line 6-9 you wrote about the Tollefson reference, that ... "another embodiment is a method of providing rapid onset treatment of depression to a patient, (p. 2, lines 10-13) which is drawn to cases which have not demonstrated treatment resistance".

My question for clarification is on the "drawn to cases", and if this is only the conclusion of the examiner, or if Tollefson indeed have had patients and studies in their application that discloses that fact of "drawn to cases".

I have not found anything in the Tollefson patent application available to me that would have specifically referred to non-TRD (non treatment resistant depression). In fact in their clinical trials (starting at page 21, line 35) they only mention "one such study" (line 37) specifically stating (on page 22 line 1) **that these were treatment resistant patients.** No reference was given to non-treatment resistant patients.

It is true, that at page 2 lines 10-13, they mention "another embodiment for rapid onset of action", (and we will address this in our reply), but it would be essential for us to know the details,

1) if the "drawn to cases" is only the examiner's conclusion and assumption that the skilled in the art would have interpreted the same, (based on p. 2, lines 10-13), **or**
2) if indeed Tollefson had shown and disclosed these "drawn to cases" of non-TRD patients. **(In the patent application they do not disclose that).**

If the second (2nd) is true, we would like to get **all the details** on that (including how they defined TRD; how and when they administered the medications on those non-TRD patients; did the non-TRD patients have their first episode or recurrent depression (and if recurrent, were there partial responders before); did they have relatives with TRD; how many weeks did they had the symptoms; what type of depressive symptoms did they have (please list them); what risk/benefit/alternative analysis they have used to justify giving the medications to the "non-TRD" patients, etc), so that in our reply we could rely on appropriate evidence and facts.
Your assistance in this matter is essential, and highly appreciated.
Please either e-mail me at: migaly1@earthlink.net or **FAX to (724)327-8887.**
If you have any question (or the Faxed pages would be more than 10-15 pages, please also call my cell phone:(724)840-0464.
Thank you,
Peter Migaly, M.D.